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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

Jeanine Enewold Goldberg

ART UNIT	PAPER
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1655

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DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

The communication filed January 7, 2002 is not fully responsive to the Office communication mailed October 5, 2001 for the reason(s) set forth below. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

The specification contains several sequences which are not identified by SEQ ID NO: nor are in the sequence listing. For example, page 5, contains two oligonucleotides; page 6, contains 4 oligonucleotides; page 8, contains 3 oligonucleotides.

Moreover, applicant's on January 7, 2002 filed a sequence listing with 3 sequences to be entered into the case. Each of these sequences do not appear to be originally filed in the application and appear to constitute new matter. Applicants are requested to identify where in the specification support for the three sequences appears.

Moreover, the claims are directed to "probes 1 and 2" however the specification does not provide sequences for "probes 1 and 2". Therefore, in order to perform a search of the claimed invention applicant is requested to identify probe 1 and 2 by SEQ ID NO: and provide support in the originally filed application for such amendment. Applicant is reminded that no new matter may be entered into the specification after the filing of the application.

Since the reply appears to be bona fide attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), applicant is given a **TIME PERIOD of ONE (1) MONTH** from the mailing date of this communication within which to correct the deficiency so as to comply with the sequence rules (37 CFR 1.821 - 1.825) in order to avoid abandonment of the application under 37 CFR 1.821(e). **EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).**

Any inquiry concerning this communication should be directed to Examiner Jeanine Goldberg, Art Unit 1634, whose telephone number is (703) 306-5817.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Notice to Comply

Application No.

09/938,013

Examiner

Jeanine Enewold Goldberg

Applicant(s)

NGUYEN ET AL.

Art Unit

1655

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other:

Applicant Must Provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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January 9, 2003

Ms. Jeanine Goldberg
US Patent and Trademark Office
Washington, D.C. 20231

RE: Application #09/938,013

Dear Ms. Goldberg:

This is in response to your letter postmarked on 12/11/02. In regards to your inquiry, I would like to make the following clarifications.

1. I am submitting the computer readable form and hard copy of the sequence listing generated from the patent in version 3.1 that include the following sequences specified in the application:

- SEQ ID #4 refers to the sequence of oligonucleotide (a) and SEQ ID #5 refers to the sequence of oligonucleotide (b) specified on page 5, lines 19 and 20 respectively in the application;
- SEQ ID #6 refers to the sequence of oligonucleotide (c), SEQ ID #7 refers to the sequence of oligonucleotide (d), SEQ ID #8 refers to the sequence of oligonucleotide (e) and SEQ ID #9 refers to the sequence of oligonucleotide (f) specified on page 6, lines 16, 17, 18 and 19 respectively in the application;
- SEQ ID #10 refers to the sequence of oligonucleotide (g), SEQ ID #11 refers to the sequence of oligonucleotide (h) and SEQ ID #12 refers to the sequence of oligonucleotide (i) specified on page 8, lines 10, 11 and 12 respectively in the application.

Also attached is the statement certifying that the content of the paper and computer readable copies is identical.

2. The three sequences filed in the sequence listing on January 7, 2002 are the sequences for probes 1, 2 and 3 specified in the application.

-The sequences of probe 1 (SEQ ID #1) and probe 2 (SEQ ID #2) are respectively portions of the whole sequences of the exons 7 and 8 of the SMN gene which were determined and published by Lefebvre et al., Ref. # 16 (see page 2, lines 14, 15 and 16 in the application). These sequences were specified but not listed in the application because they are well known and are already listed in the reference publication by Lefebvre et al., Ref. #16 stated in the reference list of the application. The sequences of the exons 7 and 8 are actually specified in the application in the following places: Page 2, lines 14, 15, 19 and 22; page 3, lines 1, 8, 9, 18 and 19; page 4, line 7; page 8, lines 3, 13 and 15; page 9, lines 8 and 9; page 12, line 23.

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-The sequence of probe 3 (SEQ ID #3) refers to a portion of the whole sequence of the HUMEF1AB gene which was determined and published by Ann et al., Ref.#20 (see page 5, lines 23, 24 and 25 in the application). This HUMEF1AB gene was used as internal standard for the control of the RT-PCR reactions. The sequence of this gene was specified but not listed in the application because it is well known and already listed in the reference publication by Ann et al., Ref. #20 stated in the reference list of the application. The sequence of the HUMEF1AB gene is actually specified in the application in the following places: Page 4, line 8; page 5, lines 23, 24 and 25; page 6, lines 18 and 19; page 8, line 4; page 9, line 9.

3. Regarding probes 1 and 2 in the claims, probe 1 is SEQ ID #1, and probe 2 is SEQ ID #2 in the sequence listing. Probe 1 (SEQ ID #1) and Probe 2 (SEQ ID #2) were used to check the presence or absence of the exons 7 and 8 in the SMN gene for the molecular diagnosis of SMA (see page 8, line 3 in the application).

Probe 3 is SEQ ID #3, directed at the human elongation factor 1-alpha (EF1A) of the HUMEF1AB gene. This HUMEF1AB gene was used as internal standard for the control of the RT-PCR reactions (see page 8, lines 4 and 5 in the application).

The sequences of the probes 1 and 2 were specified but not listed in the application because they are portions of the whole sequences of exons 7 (between base pairs 869-921) and 8 (between base pairs 922-976) respectively, already listed in the reference publication by Lefebvre et al., Ref. #16 stated in the reference list of the application.

The sequence of probe 3 was specified but not listed in the application because it is a portion of the whole sequence of the HUMEF1AB gene (between base pairs 672-723) already listed in the reference publication by Ann et al., Ref. #20 stated in the reference list of the application.

Following are the sequences and SEQ ID Numbers of the probes and oligonucleotides specified in the application and listed in the Sequence Listing:

SEQ ID # 1 Probe 1

tttcagacaa aatcaaaaag aaggaaggtg ctcacattcc ttaaattaag ga

SEQ ID # 2 Probe 2

gaaatgctgg catagagcag cactaaatga caccactaaa gaaacgatca gacag

SEQ ID # 3 Probe 3

tgtattggat tgccacacgg ctcacattgc atgcaagttt gctgagctga ag

SEQ ID # 4 Oligonucleotide (a)

cacattgcat ttg

SEQ ID # 5 Oligonucleotide (b)

ctgtctgtct ca

SEQ ID # 6 Oligonucleotide (c)
ccaggtctaa aattcaatgg

SEQ ID # 7 Oligonucleotide (d)
ctgtctgac gttctttag

SEQ ID # 8 Oligonucleotide (e)
tgtattgat tgccacacg

SEQ ID # 9 Oligonucleotide (f)
cttcagctca gcaaacttg

SEQ ID # 10 Oligonucleotide (g)
gttcagaca aaatcaaaa g

SEQ ID # 11 Oligonucleotide (h)
tccttaattt aaggaatgtg a

SEQ ID # 12 Oligonucleotide (i)
gaaatgctgg catagagcag

I hope I have adequately responded to your questions. If you have further questions, please contact me at (619) 543-3623; email: kv52nguyen@yahoo.com

Thank you for reviewing my application; I would greatly appreciate any assistance you could provide me in order to make this patent application process successful.

Sincerely,



Khue Vu Nguyen, Ph.D.

2828 University Ave., Apt. # 303
San Diego, CA 92104

Encl.: Floppy disk of sequence listing
Hard copy of sequence listing
Statement of same content
Notice to comply